SEP 2 1 2004 DE

## PATENT CASE CV06025US01

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Duane A. Burnett et al.

Examiner: To Be Assigned

For:

Group Art Unit: 1624

Substituted Azetidinone Compounds, Processes for Preparing the Same,

Formulations and Uses Thereof

Date: September 22, 2004

Serial No.: 10/791,910

Filed: 03/03/2004

## **INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicants respectfully request that the following be considered and made record, as well as the documents listed on the accompanying PTO Form 1449.

A research study was initiated on April 17, 1997 in the United States in which patients were administered capsules of the formulations of Exhibits A, B or C. Copies of the formulation Exhibits A, B and C and the informed consent form for the study (Exhibit 1) are submitted herewith for the Examiner's consideration.

A research study was initiated on October 21, 1997 in the United States in which patients were administered tablets of the formulations of Exhibits D, or E or capsules of formulation of Exhibit C. Copies of the formulation Exhibits C, D and E and the informed consent for the study (Exhibit 2) are submitted herewith for the Examiner's consideration.

A research study was initiated on November 5, 1998 in the United States in which patients were administered tablets of formulations of Exhibits D, F, G or H. Copies of the formulation Exhibits D, F, G and H and the informed consent for the study (Exhibit 3) are submitted herewith for the Examiner's consideration.

A research study was initiated on April 20, 1999 in the United States in which patients were administered tablets of the formulation of Exhibit D, optionally in coadministration with digoxin. Copies of the formulation Exhibit D and the informed consent for the study (Exhibit 4) are submitted herewith for the Examiner's consideration.

A research study was initiated on August 27, 1999 in the United States in which patients were administered tablets of the formulation of Exhibit D optionally in coadministration with Gemfibrozil 600mg tablets. Copies of the formulation Exhibit D and the informed consent for the study (Exhibit 5) are submitted herewith for the Examiner's consideration.

In the Informed Consents accompanying the above research studies, Schering's active pharmaceutical ingredient, i.e., ezetimibe, was identified as "SCH 58235" and as an "experimental drug which inhibits the absorption of cholesterol". It was not identified by its chemical name, generic name or by its chemical formula.

The Commissioner is authorized to charge Deposit Account No. 19-0365 for any additional fees deemed necessary for consideration and entry of this Information Disclosure Statement into the file record.

Serial No. 10/791,910 September 22, 2004 Page 2 of 3

PTO-1449 application.	Form be Copy(ie	consides) of t	it is requested that the documents listed on the accompanying dered and made of record in the above-identified patent these references  are attached  were filed in related filed , respectively.
(b)	No fee	is belie	ved due because:
			formation Disclosure Statement is being filed within three (3) s of the filing date of the application.
			formation Disclosure Statement is being concurrently filed with ove-identified application.
			formation Disclosure Statement is being concurrently filed with uest for Continued Examination (RCE).
	$\boxtimes$		nformation Disclosure Statement is being filed prior to the of a first Office Action on the merits.
(c)		date of	formation Disclosure Statement is being filed before the mailing any final action, notice of allowance or an action that otherwise prosecution; and
			Each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
			No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; or
			The Commissioner is hereby authorized to charge the requisite fee listed on the attached Fee Transmittal Sheet.
(d)			formation Disclosure Statement is being filed on or before the nt of the issue fee; and
			Each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
			No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; and
			The Commissioner is hereby authorized to charge the requisite fee listed on the attached Fee Transmittal Sheet.

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Page 3 of 3

The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. <u>19-0395</u>, Patent Case No. <u>CV06025US01</u>.

Respectfully submitted, SCHERING-PLOUGH CORPORATION

Dated: September 22, 2004
SCHERING-PLOUGH CORPORATION
Patent Department, K-6-1, 1990
2000 Galloping Hill Road
Kenilworth, NJ 07033-0530
Facsimile No.: (908) 298-5388

By: Name: Ann M. Cannoni

Reg. No.: 35,972 Attorney of Record

Telephone No.: (908) 298-**5024** 



Sheet \_\_1\_\_ of \_\_15

U.S. DEPARTMENT OF COMMERCE

PATENT AND TRADEMARK OFFICE

## INFORMATION DISCLOSURE STATEMENT **BY APPLICANT**

ATTY. DOCKET NO.: **APPLICATION NO.:** CV6025US01 10/791,910 APPLICANT: Duane A. Burnett et al. FILING DATE: GROUP:

	(Us	se several sheets	if necessa	ary)	03/03/2004		1624		
		F	OREIGN	PATENT DOCU	JMENTS				
		DOCUMENT	DATE	COUNTRY		CLASS	SUB-	TRANSLA N	TIO
		NUMBER					CLASS	YES	N O
	AA	BE 884722 A	12/01/80	BELGIUM		C07D	AG1K	X(abs.)	
	AB	CA 2253769	11/29/99	CANADA		A61K	31/22		
	AC	DE 2046823 A	03/30/72	GERMANY		C07C		X(abs.)	T
•	AD	DE 2521113 A	03/18/76	GERMANY		C07C	87/34	X(abs.)	
	AE	EP 0002151 A1,B1	05/30/79	EUROPE		C07C	69/67		
	AF	EP 0010299 B1	02/15/84	EUROPE		A61K	45/06		
	AG	EP 0179559 A2	04/30/86	EUROPE		C07D	405/06		
	AH	EP 0199630 A1	10/29/86	EUROPE		C07D	205/08		T
	Al	EP 0199630 B1	09/19/90	EUROPE		C07D	205/08		T
	AJ	EP 0264231 A1	04/20/88	EUROPE		C07D	205/08		T
•	AK	EP 0266896 B1	05/11/88	EUROPE		C07D	471/04		T
	AL	EP 0274873 B1	07/20/88	EUROPE		C07K	11/00		T
	AM	EP 0288973 B1	11/02/88	EUROPE		C07D	417/06		
	AN	EP 0311366 B1	04/12/89	EUROPE		C07D	471/04		
	AO	EP 0333268 A1	09/20/89	EUROPE		C07F	7/18		T
	AP	EP 0337549 A1	10/18/89	EUROPE		C07D	205/08		T
•	AQ	EP 0337549 B1	10/04/95	EUROPE		C07D	205/08		T
	AR	EP 0365364 A2	04/25/90	EUROPE		C07D	205/08		1
	AS	EP 0369686 A1	05/23/90	EUROPE		C07D	463/00		
•	AT	EP 0375527 A1	06/27/90	EUROPE		C07D	205/08	X(abs.)	$\top$
	AU	EP 0401705 A3	12/12/90	EUROPE		A61K	31/66		$\top$
	AV	EP 0415487 A2	03/06/91	EUROPE		C07D	205/08		1
	AW	EP 0455042 A1	11/06/91	EUROPE		A61K	31/19		$\top$
	AX	EP 0457514 A1	11/21/91	EUROPE		A61K	45/06		
	AY	EP 0457514 B1	08/21/96	EUROPE		A61K	45/06		T
	AZ	EP 0461548 A3	12/18/91	EUROPE		A61K	31/365		
	BA	EP 0462667 A2	12/27/91	EUROPE		C07D	205/08		
	BB	EP 0475148 A1	03/18/92	EUROPE		A61K	31/215		
	ВС	EP 0475755 B1	03/18/92	EUROPE		C07D	403/06		
	BD	EP 0481671 A1	04/22/92	EUROPE		C07D	205/08		I
	BE	EP 0482498 A3	04/29/92	EUROPE		A61K	31/66		
	BF	EP 0524595 A1	01/27/93	EUROPE		C07D	205/08		
	BG	EP 0720599 B1	07/10/96	EUROPE		C07D	205/08		
		EP 0793958 A2	09/10/97	EUROPE		A61K	9/16	X(abs)	$\Gamma$
	BI	EP 0814080 A1	12/29/97	EUROPE		C07D	267/14		
	BJ	EP 0904781 A2	03/31/99	EUROPE		A61K	31/215		
	ВК	EP 1048295 A2	11/02/00	EUROPE		A61K	31/216		$\mathbf{I}^{-}$
	BL	FR 1103113	10/31/55	FRANCE					X
	ВМ	FR 2779347	12/10/97	FRANCE		A61	31/215	X(abs.)	T
	BN	GB 861367	02/22/61	GB		A61K			I
	ВО	GB 902658	08/09/62	GB		C07D			
	BP	GB 1415295	11/26/75	GB		C07C	59/26		

FORM PTO-1449			OF COMMERCE EMARK OFFICE	ATTY. DOCKE			TION NO.:
INIEODM				APPLICANT:	<u>,,                                   </u>	10/791,9	10
INFORM	ATION DISCLOSU BY APPLICA		IEMENI	Duane A. Bu	rnett et al	<b>.</b>	
(Us	se several sheets i	if necessa	ary)	FILING DATE: 03/03/2004		GROUP: 1624	
	FC	DREIGN F	PATENT DOCU	JMENTS			
BQ	GB 2329334 A	03/24/99	GB		A61K	45/00	
BR	JP 028057	10/01/81	JAPAN				X(abs.)
BS	JP 121479	12/10/86	JAPAN				X(abs.)
BT	JP 136485	05/26/81	JAPAN			ļ	X(abs.)
BU	JP 180212	03/24/86	JAPAN			ļ	X(abs.)
BV	JP 219681	04/14/87	JAPAN		ACAIC	001/00	X(abs.)
· BW	JP 5194209 A	08/03/93	JAPAN JAPAN		A61K C07D	031/22 205/08	X(abs.) X(abs.)
BY	JP 5239020 A JP 4054182 A	1993 1992	JAPAN		C12P	017/16	X(abs.)
· BZ	JP 63017859 A	1988	JAPAN		C07D	205/08	X(abs.)
					<u> </u>	1	
CA	JP 4266869 A	1992	JAPAN		C07D	205/08	X(abs.)
CB   CC	JP 4356195 A JP 4356495	1993 12/10/92	JAPAN JAPAN			}	X(abs.) X(abs.)
CD	JP 5058993 A	1993	JAPAN			<del>                                     </del>	X(abs.)
CE	JP 61280295 A	1987	JAPAN				X(abs.)
CF	JP 95051558 B2	06/05/95	JAPAN		C07D	205/08	X(abs.)
CG	JP 91068020	10/25/91	JAPAN		CO7D	205/08	X(abs.)
СН	JP 94047573	06/22/94	JAPAN		C07D	205/08	X(abs.)
CI	WO 82/01649	05/27/82	PCT		A61K	9/52	X(abs.)
· CJ	WO 87/04429	07/30/87	PCT		C07D	205/08	
СК	WO 88/04656	06/30/88	PCT		C07D	405/04	
. CL	WO 88/05296	07/28/88	PCT		A61K	31/365	<del>    -</del>
CM	WO 91/03249	03/21/91	PCT		A61K	31/785	X(abs.)
CN	WO 92/13837	08/20/92	PCT		C07D	205/08	7.(0.00.)
CO	WO 93/02048	02/04/93	PCT		C07D	205/08	<del>                                     </del>
	1				1		<b>.</b>
СР	WO 93/07167	04/15/93	PCT		C07J	71/00	ļ
CQ	WO 93/11150	06/10/93	PCT		C07J	71/00	
CR	WO 94/00480	01/06/94	PCT		C07J	71/00	
	WO 94/14433	07/07/94	PCT		A61K	31/395	11
СТ	WO 94/17038	08/04/94	PCT		C07D	205/12	
CU	WO 94/20535	09/15/94	PCT		C07K	13/00	
CV	WO 95/04533	02/16/95	PCT		A61K	31/445	
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	<u></u>		PCT		C07D	<del></del>	/(000.)
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DD	WO 96/09827	04/04/96	PCT		A61K	31/58	
DE	WO 96/16037	05/30/96	PCT		C07D	205/08	

FORM PTO-1449			OF COMMERCE EMARK OFFICE	ATTY. DOCKE		APPLICA 10/791,9	TION NO.:
INFORM	INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT: Duane A. Bu			,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
(Us	(Use several sheets if necessary)		ary)	FILING DATE: 03/0/3/2004		GROUP: 1624	
	F(	OREIGN F	PATENT DOC	JMENTS			
DF	WO96/19450	06/27/96	PCT		C07D	205/08	
DG	WO 96/19987	07/04/96	PCT		A61K	31/35	
DH	WO 96/40255	12/19/96	PCT		A61K	45/06	
DI	WO 97/16455	05/09/97	PCT		C07H	3/04	
DJ	WO 97/18304	05/22/97	PCT		C12N	15/00	
. DK	WO 97/25042	07/17/97	PCT		A61K	31/42	
DL	WO 97/28149	08/07/97	PCT		C07D	307/79	
DM	WO 97/31907	09/04/97	PCT		C07D	263/56	
DN	WO 97/35576	10/02/97	PCT		A61K	31/44	
DO	WO 97/46238	12/11/97	PCT	<u> </u>	A61K	31/245	
DP	WO 98/01100	01/15/98	PCT		A61K		
DQ	WO 98/05331	02/12/98	PCT	•	A61K	31/45	
DR	WO 98/14179	04/09/98	PCT	:	A61K	9/50	
DS	WO 98/31360	07/23/98	PCT	1	A61K	31/19	
DT	WO 98/31361	07/23/98	PCT		A61K	31/215	X(abs.)
DU	WO 98/31366	07/23/98	PCT		A61K	31/445	
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DW	WO 98/46215	10/22/98	PCT		A61K	9/20	
DX	WO 98/47518	10/29/98	PCT .	-	A61K	31/715	
· DY	WO 98/57652	12/23/98	PCT		A61K	31/785	
DZ	WO 99/04815	04/02/99	PCT		A61K	45/00	X(abs.)
EA	WO 99/06035	02/11/99	PCT		A61K	31/00	
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EC	WO 99/08501	2/25/99	PCT				
ED	WO 99/09967	03/04/99	PCT		A61K	31/00	
EE	WO 99/12534	03/18/99	PCT		A61K	31/17	X(abs.)
EF	WO 99/11260	03/11/99	PCT		A61K	31/40	
EG	WO 99/15159	04/01/99	PCT		A61K	31/00	
EH	WO 99/15520	04/01/99	PCT		C07D	319/20	X(abs.)
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EJ	WO 99/20275	04/29/99	PCT		A61K	31/47	
EK	WO 99/20614	04/29/99	PCT		C07D	265/36	
· EL	WO 99/29300	06/17/99	PCT		A61K	9/107	
EM	WO 99/38498	08/05/99	PCT		A61K	31/00	
EN	WO 99/38845	08/05/99	PCT		C07D	213/65	
EO	WO 99/38850	08/05/99	PCT		C07D	237/32	
EP	WO 99/46232	09/16/99	PCT		C07C	62/34	X(abs.)
EQ	WO 99/47123	09/23/99	PCT		A61K	9/16	
ER	WO 99/48488	09/30/99	PCT		A61K	31/00	
ES	WO 99/66929	12/29/99	PCT		A61K	31/405	

FORM PTO-1449			OF COMMERCE EMARK OFFICE	ATTY. DOCKE		APPLICA 10/791,9	TION NO.:
INFORM	INFORMATION DISCLOSURE STATEMENT			APPLICANT:			
	BY APPLICANT  Duane A. Burnett et al.						
(Us	se several sheets	if necessa	ary)	FILING DATE: 03/03/2004		GROUP: 1624	
	F	OREIGN F	PATENT DOC	UMENTS			
ET	WO 99/66930	12/29/99	PCT		A61K	31/405	
EU	WO 00/04011	01/27/00	PCT		C07D	319/06	
EV	WO 00/07617	02/17/00	PCT		A61K	38/26	
EW	WO 00/16749	03/30/00	PCT		A61K	9/16	X(abs.)
EX	WO 97/21676	06/19/97	PCT		C07D	205/09	
. EY	WO 97/41098	11/06/97	PCT		C07D	205/09	
EZ	WO 00/18395	04/06/00	PCT		A61K	31/215	
FA	WO 00/20623	04/13/00	PCT		C12P	41/00	
FB	WO 00/23415	04/27/00	PCT		C07C	69/734	
FC	WO 00/23416	04/27/00	PCT		C07C	69/734	
FD	WO 00/23425	04/27/00	PCT		C07D	209/80	
FE	WO 00/23445	04/27/00	PCT		C07D	471/12	
FF	WO 00/23451	04/27/00	PCT		C07D	487/14	
FG	WO 00/28981	05/25/00	PCT		A61K	31/00	
FH	WO 00/31548	06/02/00	PCT		G01N	33/68	
FI	WO 00/32189	06/08/00	PCT		A61K	31/415	
FJ	WO 00/34240	06/15/00	PCT		C07D	205/08	
FK	WO 00/37057	06/29/00	PCT		A61K	9/48	
FL	WO 00/37078	06/29/00	PCT		A61K	31/44	X(abs.)
· FM	WO 00/38721	07/06/00	PCT		A61K	45/06	
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FV	WO 00/40247	07/13/00	PCT		C07D	265/26	
FW	WO 00/45817	08/10/00	PCT		A61K	31/505	
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GC	WO 00/57859	10/05/00	PCT		A61K	9/48	
GD	WO 00/57918	10/05/00	PCT		A61K	47/44	
GE	WO 00/60107	10/12/00	PCT		C12P	17/10	
GF	WO 00/63153	10/26/00	PCT		C07C	69/734	
GG	WO 00/63161	10/26/00	PCT		C07C	237/30	

FORM PTO-1449			OF COMMERCE EMARK OFFICE	ATTY. DOCKE		APPLICA 10/791,9	TION NO.:
INFORM	ATION DISCLOSU BY APPLICA	JRE STA		APPLICANT: Duane A. Bu			
(Us	se several sheets		ary)	FILING DATE: 03/03/2004		GROUP: 1624	
	FC	DREIGN F	PATENT DOCU			<del></del>	
IGН	WO 00/63190	10/26/00	PCT	DIVILIATO	C07D	265/38	l I
GI	WO 00/63196	10/26/00	PCT		C07D	277/04	
GJ	WO 00/63209	10/26/00	PCT .		C07D	471/04	
GK	WO 00/63703	10/26/00	PCT		G01N	33/92	
GL	WO 00/69412	11/23/00	PCT		A61K	9/127	
. дм	WO 00/69445	11/23/00	PCT		A61K	31/785	
GN	WO 00/72825	12/7/00	PCT		A61K	9/14	
GO	WO 00/72829	12/07/00	PCT		A61K	9/48	
GP	WO 00/75103	12/14/00	PCT		C07C	235/60	X(abs.)
GQ	WO 00/76482	12/21/00	PCT		A61K	9/48	Ì
GR	WO 00/76488	12/21/00	PCT		A61K	31/00	
GS	WO 00/78312	12/28/00	PCT		A61K	31/421	
GT	WO 00/78313	12/28/00	PCT		A61K	31/422	
GU	WO 01/00579	01/04/01	PCT		C07D	213/65	
GV	WO 01/00603	01/04/01	PCT		C07D	277/24	
GW	WO 01/08686	02/08/01	PCT		A61K	31/495	
GX	WO 01/12176	02/22/01	PCT		A61K	31/16	
GY	WO 01/12187	02/22/01	PCT		A61K	31/404	
GZ	WO 01/12612	02/22/01	PCT		C07D	257/04	
• НА	WO 01/14349	03/01/01	PCT		C07D	277/34	X(abs.)
НВ	WO 01/14350	03/01/01	PCT		C07D	277/34	X(abs.)
HC	WO 01/14351	03/01/01	PCT		C07D	277/34	X(abs.)
HD	WO 01/15744	03/08/01	PCT		A61K	49/00	
HE	WO 01/16120	03/08/01	PCT		C07D	263/32	
HF	WO 01/17994	03/15/01	PCT		C07D	413/12	
HG	WO 01/18210	03/15/01	PCT		C12N	15/12	
НН	WO 01/21181	03/29/01	PCT		A61K	31/675	X(abs.)
HI	WO 01/21259	03/29/01	PCT		A61P		
HJ	WO 01/21578	03/29/01	PCT		C07C	235/60	X(abs.)
HK	WO 01/21647	03/29/01	PCT		C07K	14/00	
HL	WO 01/22962	04/05/01	PCT		A61K	31/435	
НМ	WO 01/25225	04/12/01	PCT		C07D	317/18	
HN	WO 01/25226	04/12/01	PCT		C07D	327/04	
НО	WO 01/30343	05/03/01	PCT		A61K	31/40	
HP	WO 01/32161	05/10/01	PCT		A61K	31/00	
HQ	WO 01/35970	05/25/01	PCT		A61K	35/76	
HR	WO 01/40192	06/07/01	PCT		C07D	217/26	X(abs.)

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	FC	DREIGN F	PATENT DOC	UMENTS		
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HV	WO 01/76632	10/18/01	PCT		A61K	45/06
HW	WO 02/50090	06/27/02	PCT		C07H	15/26
. HX	WO 02/058696	08/01/02	PCT		A61K	31/397
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IK	WO 02/50027	06/27/02	PCT			
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	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)					
IY	Exhibit A: SCH 58235 Micronized (ezetimibe), D					
IZ	Exhibit B: SCH 58235 (ezetimibe), Drug Formul					
JA	Exhibit C: SCH 58235 (ezetimibe), Drug Formul					
JB	Exhibit D: SCH 58235 (ezetimibe), Drug Formul					
JC	Exhibit E: SCH 58235 (ezetimibe), Drug Formula					
JD	Exhibit F: SCH 58235 (ezetimibe), Drug Formula					
· JE	Exhibit G: SCH 58235 (ezetimibe), Drug Formul					
JF	<b>Exhibit H:</b> SCH 58235 (ezetimbe), Drug Formul					
. JG	Exhibit 1: Master Sheet for the SCH 58235 and Research Institute (Protocol No. C906-411), page		uy, <i>Scriening-Plougn</i>			
JH	Exhibit 2: Medical Research Study #1055/97, So		v of Single Oral Doses			
	of Two Prototype Tablet Formulations and the Re					
	Normal Male Volunteers: A Four Way Crossover					
	Peninsular Testing Corporation, page 106-112	•	•			
JI	Exhibit 3: Consent Form to Participate in a Rese	earch Study, "A Phase II	Double Blind Dose			
	Response Investigation of Efficacy and Safety of					
	Placebo in Subjects with Primary Hypercholestero					
	(Protocol No. C98-010), page 1558-1566	, 0				
JJ	Exhibit 4: Medical Research Study #1096/99, So	CH 58235: Pharmacokin	etic Pharmacodynamic			
	Drug Interaction Study with Digoxin in Healthy Vo					
·	Peninsular Testing Corporation, page 124-130	·	•			
JK	Exhibit 5: Informed Consent, "SCH 58235: Asse	essment of Multiple-Dose	Drug Interaction			
	Between 58235 and Gemfibrozil in Healthy Volun					
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